Environmental Monitoring and Contamination Control

Overview

Establishing a comprehensive microbial control strategy for your company is a key component of contamination control and an expectation of regulatory agencies. This fact is highlighted in the revised version of Annex 1. Contamination control for sterile, non-sterile, low-bioburden and cell and gene therapy manufactured products will all be included in this course with discussions around the differences in each area.

This two-day training course will be a complete review of all aspects of a contamination control program. A review of the regulation and requirements will be performed along with discussions around practical deployment of the requirements as well as challenges and solutions.

This interactive course will provide a detailed review on how to establish and maintain an effective risk-based EM Program. Cleanroom classification, HVAC Qualification (EMPQ) and routine environmental monitoring requirements and best practices will be discussed along with establishment of cleaning / disinfection programs and disinfectant efficacy testing. EM alert / action level setting, EM excursion investigations and microbial identifications will be discussed.

Who Should Attend

- Manufacturing - Supervisors / Managers / Specialists
- Quality Control - Managers / Specialists / Technicians / Microbiologists
- Quality Assurance - Managers / Specialists / Technicians / Microbiologists
- Validation - Supervisors / Managers / Specialists / Technicians
- Engineering - Supervisors / Managers / Specialists / Technicians

Learning Objectives

- Apply current regulatory guidance to your environmental monitoring program and contamination control strategies
- Review and discuss the NEW contamination control requirements in the revised Annex 1
- Understand the requirements of cleanroom classification and ongoing monitoring according to ISO 14644-1,2
- Describe and discuss industry best practice and requirements for establishing cleaning and disinfection programs
- Discuss disinfectant efficacy studies
- Describe how to implement environmental monitoring risk assessments
- Understand differences in EM requirements for non-sterile, low-bioburden, cell and gene therapy and sterile product manufacturing
- Discuss how to create and perform EM performance qualifications (EMPQ)
- Compare and contrast new and existing environmental monitoring equipment
- Explain how to conduct EM investigations
- Describe how to establish EM alert and action levels and how to prepare meaningful trend reports
- Describe and review microbial identification instruments and methods
- Understand how to establish the best microbial control strategy for your company

Marsha Steed, *Director of Global Microbiology, bluebird bio*

Marsha Steed has over 25 years of experience as a Microbiologist working in the Pharmaceutical, Biotechnology and Medical Device fields. Marsha has a Bachelor in Biology from Western New England University in Springfield, MA. She was a Senior Consultant for ValSource and in this role, helped companies implement quality risk management into their quality management systems and validation programs. Marsha specializes in helping companies develop risk based environmental monitoring programs and perform microbial risk assessments. She also provides many training courses and webinars for aseptic processing, cleanroom classification and facility startup. Marsha is an expert in Cell and Gene Therapy. Currently she holds the position as Director of Global Microbiology at bluebird bio.

16 August 2019

Thursday, 5 September 2019 — 9:00 – 18:00

9:00 **Welcome and Introduction**

9:15 **Guidance and Regulations**
- FDA Sterile Guidance
- Annex 1 2008 and revised version
- ISO 14644
- USP / EP
- PDA TR13 'Fundamentals of an Environmental Monitoring Program'

10:30 **Coffee Break**

11:00 **Classification of Cleanrooms and EMPQ**
- ISO 14644-1 & 2
- Selection of representative sample locations
- Use of risk
- Periodic classification
- Baseline studies
- Environmental Monitoring risk assessments
- Static and Dynamic EMPQ

12:30 **Lunch Break**

13:30 **Establishing Cleaning and Disinfection Programs**
- Selecting agents
- Mopping
- Rotations
- Disinfectant Efficacy Studies

15:30 **Coffee Break**

16:00 **EM Risk Assessment Methods**
- EM-REM
- FMEA
- HACCP

18:00 **End of Day 1**

Friday, 6 September 2019 — 9:00 – 16:30

9:00 **Environmental Monitoring Equipment**
- Sampler types for viable and nonviable
- Microbial ID EQ

9:30 **Environmental Monitoring (EM)**
- Non-viable particulates
- Viable air and surface
- Surface particulates
- Personnel EM
- Frequency of monitoring
- Number of samples
- Growth promotion of media
- Establishing EM SOPs
- In-house vs. CTO options
- EMPQ

10:30 **Coffee Break**

11:00 **EM for Different Manufacturing Processes**
- Sterile Products
- Low Bioburden
- Non-sterile
- Cell and Gene Therapy

12:30 **Lunch Break**

13:30 **EM Trending**
- Establishing alert and action levels
- Meaningful trending and reporting
- Use of EM Software

14:30 **EM Investigations**
- Conducting EM Investigations

15:00 **Coffee Break**

15:30 **Microbial Identifications**

16:00 **Summary, Q&A**

16:30 **End of Course**